UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

25213 7590 08/28/2007

HELLER EHRMAN LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/693,558	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-82* is/are pending in the application.

4a) Of the above claim(s) *65 and 72-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-64 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 57-82 ARE PRESENTED FOR EXAMINATION

Continued Examination Under 37 CFR § 1.114

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 10/25/2006 has been entered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 57-71 in the reply filed on 6/18/2007 is acknowledged. The traversal is on the ground(s) that Groups I, II, and III are not independent and distinct and that because all groups have been given the same classification, there is no reason to separate the inventions. This is not found persuasive because as set forth in the Office Action mailed 5/18/2007, the composition of Group I comprises a compound of Formula (I) **and** a compound selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb. The method of Group II does not require a compound of Formula I and thus the search of Group II would not encompass the same subject matter as that of Group I. The method of Group II is drawn to an independent and distinct invention from that of Group I because a method of reducing side effects of a cancerostatic or immunosuppressive agent comprising administering a "compound having vitamin PP activity" does not require the composition of Group I. Thus, a search for: a) compounds of Formula I; b) compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb; or c) methods of reducing side effects of a

cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity are not coextensive in scope and require searching different databases and utilizing different search criteria. The requirement is still deemed proper and is therefore made **FINAL**.

Claims 72-82 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/18/2007.

Applicant's election of the species N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide as a compound of Formula I and nicotinamide as the compound having vitamin PP activity in the reply filed on 6/18/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the species election requirement, the election of species has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 65 is withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected specie having vitamin PP activity, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/18/2007.

Priority

This instant application is a continuation of PCT/EP99/02686, filed April 21, 1999 and claims priority to German Application No. 19818044.6, filed April 22, 1998.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 57-64 and 66-71 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. To satisfy 35 U.S.C. § 101, an invention must be "useful." Courts have recognized that the term "useful" used with reference to the utility requirement can be a difficult term to define; however, Courts have used the labels "practical utility," "substantial utility," or "specific utility" to refer to this aspect of the "useful invention" requirement of 35 U.S.C. § 101. A "specific utility" is specific to the subject matter claimed and can "provide a well-defined and particular benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). As the claims point out, the application relates to pharmaceutical compositions comprising a compound of Formula (I) and at least one compound having vitamin PP activity which is selected from the group of compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb. According to Applicants' specification, the compounds of Formula (I) are used as cancerostatic agents and/or tumor inhibitors or immunosuppresive agents (page 6). Thus, it appears that the claimed pharmaceutical compositions are intended for use in treating cancer, tumors, or immunological disorders. The compounds having vitamin PP activity are alleged to have cyto-protective activity for the "prevention, reduction or elimination of side effects and/or neutralization of the effects of cancerostatic agents or immunosuppresive agents", especially of the compounds of Formula (I) (pages 4-5). Applicants predicate patentability of their claimed pharmaceutical compositions

partially on the advantage of the compositions possess as drugs, medicaments and the like. In this regard, the specification states, *inter alia*:

> Therefore, it is an object to find a method which helps to suppress, neutralize or at least reduce, to a degree which is easy to bear for patients, the side-effects of different degrees of severity associated with chemotherapy, especially of tumors, or with the chemotherapeutic immunosuppression or with prevention of metastasis formation or anti-proliferative treatment with pharmaceuticals.
>
> A further object is also to entirely eliminate the side-effects which are already reduced in comparison to customary tumor inhibitors of the compounds according to the general formula (I), and, in individual cases, to still further diminish particular individual patient sensitivity.
>
> Surprisingly, it has now been found that, in contrast to the effects and/or effectiveness-increasing activities of nicotinic acid or nicotinic acid amide in connection with radiation therapy discussed at the beginning, these compounds can be used for preventing side-effects or **neutralizing the cell growth-inhibiting activity** of cancerostatic and/or tumor-inhibiting chemotherapeutic agents based on an opposing effect which has not yet been explained scientifically.
>
> Hence, the invention relates to the use of compounds with vitamin PP activity as a cyto-protective agents for the prevention, reduction or elimination of side-effects and/or **neutralization of the effects** of cancerostatic agents or immunosuppressive agents, especially of compounds from the series of substituted pyridylalkane, pyridylalkene and pyridylalkine acid amides of the general formula (I), in diagnostics or cytostatic or immunosuppressive chemotherapy, optionally in combination with radiation therapy.
>
> Furthermore, it relates to the use of vitamins of the group PP as cyto-protective agents production of medicaments for prevention, reduction or elimination of side-effects and/or **neutralization of the effects** of cancerostatic agents or immunosuppressive agents, especially compounds from the series of substituted pyridylalkane, pyridylalkene and pyridylalkine acid amides in diagnostics or cytostatic, anti-proliferative or immunosuppressive chemotherapy, optionally in combination with radiation therapy. The use according to the invention in the application of compounds of the general formula (I) can also be in connection with their administration as an abortive agent.

Thus, the compositions as claimed are set forth as therapeutics that will be administered to patients so as to affect some biological response. However, Applicants have not set forth the utility of the claimed compositions with any reasonable specificity, especially considering the broad scope of the claims. At the present time, there is no evidence of record that would indicate that the compositions as claimed have the utilities as set forth in the specification. Further, the

claims literally encompass millions of possible compounds. "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230. In the instant case, the claimed compositions, encompassing millions of possible compounds and combinations of compounds, fail to provide an immediate benefit to the public because it is not apparent exactly which combination of compounds, out of the millions of possible combinations, will have the biological affects alleged in the specification. As such, the instant invention appears to be, at this time, a mere scientific curiosity. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Accordingly, the Examiner cannot accept the alleged utility of the claimed compositions absent clear and convincing proof thereof.

The compositions containing compounds having vitamin PP activity have been alleged to be cyto-protective agents for the prevention, reduction or elimination of side-effects and/or neutralization of the effects of cancerostatic agents or immunosuppressive agents, especially compounds from the series of substituted pyridylalkane, pyridylalkene and pyridylalkine acid amides in diagnostics or cytostatic, anti-proliferative or immunosuppressive chemotherapy. Thus, it is apparent that the claimed compositions are intended to be used as anticancer or immunosuppresive therapy. However, it is disclosed in the Specification that the addition of a compound having "vitamin PP activity" to a composition comprising a cancerostatic or immunoosuppressive agent **neutralizes** the cancerostatic or immunosuppressive activity of the

active agent. Thus, it is not seen what benefit the claimed compositions would have in the treatment of a human patient if the net effect of such compositions is neutralization of the alleged cancerostatic, antitumor, or immunosuppressive properties of the claimed compounds of Formula I.

Further, out of the literally millions of possible compounds of Formula (I) as recited in the claims, only **one** such compound in combination with only **two** different agents having vitamin PP activity was actually tested. In the experiments provided in the specification, nicotimamide actually decreased the growth-inhibiting effect of K22.097 in human leukemia cells (Table 1). Thus, while nicotinamide may decrease the cytotoxicity of K22.097, it also appears to inhibit its efficacy. If such is the case, it is not apparent what utility the claimed compositions have in treating a human patient if the beneficial pharmacological effects of compounds of Formula I are neutralized or decreased in the presence of an agent having vitamin PP activity (*e.g.*, nicotinamide).

Thus, in the absence of clear and convincing proof that the claimed compositions have therapeutic use in treating human patients, it is the Examiner's position that the instantly claimed invention lacks a substantial, specific utility. It is simply not reasonable to accept Applicants' assertion that the millions of possible combinations instantly claimed have any beneficial utility in treating a human patient.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

> pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-64 and 66-71 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

---

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to pharmaceutical compositions comprising a compound of Formula (I) and a compound having vitamin PP activity selected from compounds of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. The artisan using Applicant's invention would generally be a physician with a M.D. degree and several years of experience.

That factor is outweighed, however, by the unpredictable nature of the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical*

Corporation, et al. v. Wright, et al., 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

Firstly, it is noted that Applicants do not disclose the mechanism of action or biological target of the compounds of Formula I recited in the claims. Further, the compounds having vitamin PP activity are asserted to be useful "for preventing side-effects or neutralizing the cell growth-inhibiting activity of cancerostatic and/or tumor-inhibiting chemotherapeutic agents based on an opposing effect which has not yet been explained scientifically" (page 4 of specification). Thus, it is also apparent that Applicants do not know how or why the compounds having vitamin PP activity cause the biological effect asserted in the specification. As such, it is apparent that the claimed subject matter is *prima facie* unpredictable because the mechanism of action of the claimed compounds of Formula I is not known and the reason the claimed vitamin PP compounds neutralize the biological effects of compounds of Formula I is also not known.

Secondly, as illustrative of the state of the art with respect to the predictability of treating cancer, the examiner cites Sausville *et al.* (Cancer Research, 2006, vol. 66, pages 3351-3354) and Johnson *et al.* (British J. of Cancer, 2001, 84(10):1424-1431).

Sausville *et al.*, cited for evidentiary purposes, teaches that traditionally explored tumor model systems are insufficient to predict how actual human beings will respond to treatment in

the clinic (page 3351, left column). Even when drugs with evidence of anticancer activity in preclinical *in vivo* models are given their maximum tolerated dose in humans, they frequently fail to produce useful activity in humans (*id.*). Also, with regard to unpredictability, Johnson *et al.*, also cited for evidentiary purposes, teach that the *in vivo* activity of 39 different agents in a particular histology in a tumor model did not correlate to activity in the same human cancer. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, the mode of action of anticancer agents is often unknown or very unpredictable and administration of such agents is often accompanied by undesirable side effects.

These articles plainly demonstrate that the art of treating cancer, particularly in humans, is extremely unpredictable, particularly in the case of a single compound or genus of compounds being used to treat any and all cancers.

2. The breadth of the claims

The claims are extremely broad insofar as they disclose pharmaceutical compositions comprising a compound of Formula I and a compound of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb, which are asserted to be useful in treating human patients. The claims literally encompass millions of possible compounds in millions of possible combinations.

3. The amount of direction or guidance provided and the presence or absence of working examples

With respect to making the claimed compounds, the specification provides minimal guidance or direction. In fact, no particular synthetic methodologies are provided that could be

reasonably modified to make even a limited sub-genus of claimed compounds of Formula I, let alone a reasonable number of the millions of compounds encompassed by the claims. The scope of the claimed subject matter is so broad that it would take undue experimentation to make a number of compounds of Formula I that bears any reasonable correlation to the scope the claims.

As discussed *supra*, the claimed pharmaceutical compositions are intended for use in treating human subjects, for example, as cancerostatic, antitumor, or immunosuppressive compositions. While a lack of substantial and specific utility is set forth above, the claims also lack enablement for the intended use of the claimed compositions. For example, only **two** compounds of Formula I (out of millions of possible compounds) in combination with only **two** specific agents having vitamin PP activity were actually tested. In one example, the combination resulted in less efficacy in inhibiting leukemia cell growth than the compound of Formula I alone. In another example, the mortality of mice administered a compound of Formula I appears to have decreased when the compound was co-administered with nicotinamide. However, the testing of one specific combination of compounds cannot be said to reasonably correlate with the broad scope of the claimed subject matter. It is not at all predictable if any other combinations of compounds will have any effect, beneficial or otherwise.

Further, for the claimed compositions to have any use in treating human patients (*i.e.*, as cancerostatic, antitumor, or immunosuppresive compositions), they must be both therapeutically effective and have minimized side-effects as asserted in the specification. In this regard, Applicants have not provided any methods to assess the efficacy and neutralization of side-effects of compounds of Formula I at the same time (*e.g.*, animal models of chemotherapeutic side-effects).

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed compositions could be predictably used as a treatment for all cancerous cell growth or immunological disorders as inferred in the claims and contemplated by the specification.

Genentech Inc. vs. Nova Nordisk states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

In the instant case, Applicants have presented a general idea that because nicotinamide reduced the efficacy of one compound of Formula I, that any and all compounds of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb in combination with any and all compounds of Formula I must therefore, *a priori*, be useful in the treatment of cancerous cell growth, tumors, and as immunosuppressive compositions while exhibiting elimination of side-effects associated with such treatment. However, the claims encompass a multitude of compounds (literally millions) having a plethora of chemically and biologically distinct substituents and further encompass millions of different possible combinations of such compounds. Applicants appear to have made and tested two compounds of Formula I with very similar core structures (K22.097 and K22.175). Only nicotinamde and nicotinic acid are exemplified as agents having vitamin PP activity in the examples.

It is evident that a very small percentage of the claimed compounds were actually synthesized and tested by Applicants and all of the synthesized compounds were related in structure. Thus, the compounds actually synthesized and screened by Applicants do not correlate in scope with the claimed subject matter. Given the extremely diverse compounds encompassed by the claims and the limited examples provided in the specification, the skilled artisan cannot predict what structural features (other than those of the compounds actually synthesized) are important for *efficacy* of the claimed compounds. In other words, the structure activity relationship demonstrated in the examples is limited to a very small sub-genus of compounds (e.g., compounds of Formula I wherein G is piperidine).

Determining if any particular claimed composition would treat any particular disease or condition would require synthesis of the compound, formulation into a suitable dosage form, and subjecting it to clinical trials or to testing in an assay known to correlate to clinical efficacy of such treatment. This is undue experimentation given the limited guidance and direction provided by Applicants. As noted *supra*, even *in vitro* and *in vivo* assays do not always correlate to efficacy in humans and are not generally predictive of clinical efficacy. Further, the fact that nicotinamide appears to reduce the efficacy of the claimed compounds, leads one to reasonably doubt that a combination comprising a compound of Formula I and a compound of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb could predictably be used to treat any human disease or disorder.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim 66 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The instant claim recites "a compound having vitamin PP activity or an ester thereof". There is insufficient written description for compounds having vitamin PP activity, other than compounds of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and

Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicants have failed to provide any structural characteristics, chemical formula, name(s) or physical properties, aside from compounds of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb, that would provide adequate written description of the genus of compounds having vitamin PP activity. Absent an adequate written description of such compounds having vitamin PP activity and esters thereof, it is not apparent that Applicants were actually in possession of, and intended to be used within the context of the present invention, any other compounds having vitamin PP activity, other than those of formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, and Vb as disclosed in the specification.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 21, 2007

8/24/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER